REMARKS

Claims 1-19 were examined. Claims 1, 3, 7 and 11 are amended. Claims 1-19 remain in the application.

The Patent Office rejects claims 1-19 under 35 U.S.C. §102(e) and claims 6-10 and 13-15 under 35 U.S.C. §103(a). Reconsideration of the claims is respectfully requested in view of the above amendments and the following remarks.

A. 35 U.S.C. §102(e): Rejection of Claims 1-19

The Patent Office rejects claims 1-19 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,391,005 of Lum et al. (Lum). Lum describes an apparatus such a needle that may penetrate skin. The apparatus includes a shaft with conductive ends for sensing the impedance of tissue about a tip of the shaft. Electrical impedance is sensed between two points.

Independent claim 1 is not anticipated by Lum, because Lum does not describe an apparatus including a needle, and a device coupled to the needle comprising a conductive component adapted to move in response to a resistive force. A representation of such a device is illustrated in **Figures 8** and **9** of the Application and the accompanying text where movement of a conductive component provides an electrical indication of a needle penetrating into a tissue wall. In response to movement of conductive gasket 808 caused by a resistive force by the tissue wall, the contact between a conductive gasket 808 and contact ring 810 occurs. The distance traveled by conductive gasket 808 corresponds to a depth of tissue penetration by the needle. Lum describes measuring impedance between contacts, not measuring a depth of tissue penetration by movement of a contact.

Claims 2-12 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-12 are not anticipated by Lum.

Independent claim 13 is not anticipated by Lum, because Lum does not disclose an apparatus including a spring-loaded needle, a first conductive element coupled to the needle and slidably movable, and a second conductive element arranged to generate an electrical signal upon contact with the first conductive element. As noted above, Lum describes measuring impedance between context.

For the above stated reasons, claim 13 is not anticipated by Lum. Claims 14-15 depend from claim 13 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 13, claims 14-15 are not anticipated by Lum.

Independent claim 16 is not anticipated by Lum, because Lum does not describe a method including penetrating a tissue wall with a needle assembly, where the needle assembly includes a first conductive element and a second conductive element and the penetration of a tissue wall allows the first conductive element to slidably move toward the second conductive element. As noted above, Lum describes measuring impedance between contacts.

For the above stated reasons, claim 16 is not anticipated by Lum. Claims 17-19 contain all the limitations of claim 16. For at least the reasons stated with respect to claim 16, claims 17-19 are not anticipated by Lum.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 1-19 under 35 U.S.C. §102(e) over Lum.

B. 35 U.S.C. §102(e): Rejection of Claims 1-5, 11-12 & 16-19

The Patent Office rejects claims 1-5, 11-12 and 16-19 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,706,016 of Cory et al. (Cory). Cory describes a nerve stimulator that includes a needle that may be advanced into the skin. Current is supplied to the needle and the needle advanced into a muscle until muscle twitch is achieved indicating the needle is close to a nerve. The needle is able to determine depth beneath the skin by using a linear

resistance coating 106 connected to a voltage source via an electrical pin connector 103 and an electrical trace. Cory, col. 7, lines 19-24.

Cory describes depth determination by resistance measurement including an electrode located remotely on a skin surface and resistance coating 106. In operation, a voltage signal from a voltage source is applied to resistance coating 106. A circuit is completed through the linear resistance coating as it penetrates the skin. The return electrode detects the signal and provides a detected signal to a nerve stimulator. See Cory, col. 7, line 58 through col. 8, line 4. The Patent Office points to indelible marks 113 as conductive elements, but Applicant is unable to find any teaching that such marks are conductive.

Independent claim 1 is not anticipated by Cory, because Cory does not describe an apparatus including a needle and a device coupled to the needle wherein the device comprises a conductive component adapted to move in response to a resistive force and wherein a movement corresponds to a depth of tissue penetration. Cory measures penetration depth by a resistance measurement between an electrode on a skin surface and linear resistance coating 106.

For the above stated reasons, claim 1 is not anticipated by Cory, claims 2-5 and 11-12 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-5 and 11-12 are not anticipated by Cory.

Independent claim 16 is not anticipated by Cory, because Cory does not describe a method including penetrating a tissue wall with a needle assembly wherein the needle assembly includes a needle, a first conductive element coupled to the needle, and a second conductive element and the penetration with the needle assembly allows the first conductive element to slidably move toward the second conductive element. As noted above, Cory describes measuring depth penetration by resistance measurement between electrodes.

For the above stated reasons, claim 16 is not anticipated by Cory. Claims 17-19 depend from claim 16 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 16, claims 17-19 are not anticipated by Cory.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 16-19 under 35 U.S.C. §102(e).

C. 35 U.S.C. §103(a): Rejection of Claims 6-10 & 13-15

The Patent Office rejects claims 6-10 and 13-15 under 35 U.S.C. §103(a) as obvious over Cory in view of U.S. Patent No. 6,569,144 of Altman (Altman). Altman is cited for teaching a spring-loaded needle that is used to retract the needle after it penetrates a tissue. According to the Patent Office, it would have been obvious for one skilled in the art to modify Cory to include the use of a spring-loaded needle in order to automatically withdraw the needle.

Claims 6-10 depend from claim 1 and therefore contain all the limitations of that claim. Claims 6-10 are *prima facie* not obvious over the cited references, because the cited references do not describe an apparatus including a needle and a device coupled to the needle comprising a conductive component adapted to move in response to a resistive force and wherein the movement corresponds to a depth of tissue penetration. As noted above, Cory teaches resistance measurements between electrodes. There is no motivation in Cory or Altman to include a device on the needle including a conductive that moves in response to a resistive force and where such movement corresponds to a depth of tissue penetration. Combining Altman and Cory would yield a spring-loaded retractable assembly that measures resistance between electrode.

Independent claim 13 is *prima facie* not obvious over the cited references, because the references do not disclose an apparatus including a spring-loaded needle, a first conductive element, and a second conductive element wherein the first conductive element is slidably movable upon contact with and penetration into a tissue wall and the second conductive element

is arranged to generate an electrical signal upon contact with the first conductive element. As noted above, Cory does not disclose movement of conductive element or contact between conductive elements. Adding a spring-loaded withdrawal mechanism to the design of Cory would not achieve the elements of the apparatus of claim 13. Further, there is no motivation from the cited references for an apparatus including a first conductive element and a second conductive element when the first conductive element is slidably movable and the second conductive element is arranged to generate electrical signal upon contact with the first conductive element.

For the above stated reasons, claim 13 is not obvious over the cited references. Claims 14-15 depend from claim 13 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 13, claims 14-15 are not obvious over the cited references.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 6-10 and 13-15 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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Dated: 11/16/04

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I hereby certify that this correspondence is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Nedy Calderon 11/16/04

Nedy Calderon Date